

Additional Information Relevant to Topic #1

Validation of Procedures to Prevent Contamination and Cross-Contamination with TSE Agents of human Tissue Intended for Transplantation

- Brown P, Gibbs C J, Jr., Rodgers Johnson P, Asher D M, Sulima M P, Bacote A, Goldfarb L G and Gajdusek D C. Human spongiform encephalopathy: The National Institutes of Health series of 300 cases of experimentally transmitted disease. Annals of Neurology (Boston MA) 1994;35(5): 513-529.
- Brown P, Preece M, Brandel J P, Sato T, McShane L, Zerr I, Fletcher A, Will R G, Pocchiari M, Cashman N R, d'Aignaux J H, Cervenakova L, Fradkin J, Schonberger L B and Collins S J. Iatrogenic Creutzfeldt-Jakob disease at the millennium. Neurology 2000;55(8): 1075-81.
- Hannah E L, Belay E D, Gambetti P, Krause G, Parchi P, Capellari S, Hoffman R E and Schonberger L B. Creutzfeldt-Jakob disease after receipt of a previously unimplicated brand of dura mater graft. Neurology 2001;56(8): 1080-3.
- Hogan RN, Brown P, Heck E, Cavanagh HD. Risk of prion disease transmission from ocular donor tissue transplantation. Cornea 1999; 18(1): 2-11.
- Taylor D M. Inactivation of transmissible degenerative encephalopathy agents: A review. Vet J 2000;159(1): 10-7.
- Suitability Determination for Donors of Human Cellular and Tissue-Based Products, Proposed rule, 64 Federal Register, 52696-52723, September 30, 1999.
- Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement; Proposed rule, 66 Federal Register, 1508-1559, January 8, 2001.
- Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation – Final Guidance, March 2002.

Recent Information Related to TSEs (day 2):

Bosque P J, Ryou C, Telling G, Peretz D, Legname G, DeArmond S J and Prusiner S B. Prions in skeletal muscle. Proc Natl Acad Sci U S A 2002;99(6): 3812-7.

Shaked G M, Shaked Y, Kariv-Inbal Z, Halimi M, Avraham I and Gabizon R. A protease-resistant prion protein isoform is present in urine of animals and humans affected with prion diseases. J Biol Chem 2001;276(34): 31479-82.

Additional Information Relevant to Topic #2:

1. Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products, January 2002. <http://www.fda.gov/cber/whatsnew.htm>
2. Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)- **6/14/2002** - <http://www.fda.gov/cber/whatsnew.htm>